

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 17 2004

Robert J. Sloan  
Sr. Regulatory Service Associate  
H & S Chemicals Division  
c/o Lonza, Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

Subject: **Formulation HWS-512**  
EPA Registration Number 47371-191  
Application Dated February 19, 2004  
EPA Receive February 24, 2004

Dear Mr. Sloan:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

**Proposed Amendment:**

- adding of claims against two organisms
- adding of use directions
- other minor changes as shown on the highlighted copy of the proposed label

**Data Summary:**

1. The proposed label claims that the product, Formulation HWS-512, is an effective disinfectant against the Human coronavirus in the presence of 400 ppm hard water and a 5% organic soil load when used at a 1:512 dilution for a contact time of 10 minutes, as supported by the submitted efficacy data.

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Please Note: Acceptance of this data to support a label claim for Human coronavirus does not support a label claim for this product as a disinfectant against the causative agent of Severe Acute Respiratory Syndrome (SARS).

2. Upon review of the initial data package, efficacy studies pertaining to bactericidal stability were not submitted. At that time, the Agency requested that the proposed label claims (page 4 ) regarding the storage of the use solution for up to one year be removed from label. You have now verified in a recent submission that the test substance used in the efficacy testing was more than a year old. Therefore, the proposed bactericidal stability claims are acceptable. A revised data citation matrix addressing these comments from the Agency was included in the submission.

**Conditions**

**Revise label as follows:**

1. The proposed label indicates that the product, Formulation HWS-512, may be used to disinfect foot spas (page 3 of proposed label). You must remove this item from the label, or provide specific instructions on the use of this product to disinfect foot spas.
2. The proposed label indicates that the product, Formulation HWS-512, may be used on outdoor furniture (page 3 proposed label; right column). Outdoor furniture may be manufactured with wood and upholstery, which are porous materials. We recommend that the label be revised to indicate the use of Formulation HWS-512 on "outdoor furniture, except non-porous surfaces such as wood, upholstery, etc.

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**General Comments:**

A copy of the stamped label acceptable w/conditions is enclosed. Submit a copy (1) of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,



*for*

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosed (Efficacy Review July 30, 2004)

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**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER. CORROSIVE.** Causes irreversible eye damage and skin burns. Harmful if inhaled, swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber or chemical resistant). Avoid breathing spray. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

*(Note to reviewer. If container size is 5 gallons or greater, the following Environmental Hazards statements will be used.)*

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 47371-191**

**FORMULATION HWS-512**

**ONE-STEP DISINFECTANT**

**GERMICIDAL DETERGENT AND DEODORANT**

Disinfectant	Pseudomonacidal
Staphylocidal	Salmonellacidal
Bactericidal	Fungicidal
Mildewstatic	*Virucidal

FLORAL / CITRUS / FRESH / CLEAN / LEMON / PINE / MINT (scent) (fragrance) (odor) (scented)

Active Ingredients:

Didecyl dimethyl ammonium chloride.....	20.28%
n-Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%) dimethyl benzyl ammonium chloride .....	13.52%
Inert Ingredients:.....	66.20%
Total .....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See (right) (left) (side) (back) panel for Precautionary Statements and First Aid

EPA Reg. No. 47371-191  
EPA Est. No. *(insert Est. No. here)*  
NET CONTENTS *(insert container size here)*

H&S CHEMICALS DIVISION  
c/o LONZA INC.,  
17-17 ROUTE 208, FAIR LAWN, NJ 07410

**ACCEPTED**  
**with COMMENTS**  
**in EPA Letter Dated:**

AUG 17 2004

(Note to reviewer: The following is considered optional marketing language:)

- Concentrate (Concentrated)
- Neutral (Neutral pH)
- Disinfects (Disinfectant)
- Cleans (Cleaner)
- Deodorizes (Deodorizer)

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO<sub>3</sub>) in the presence of a moderate amount of soil (5% organic serum) according to the AOAC Use-dilution Test. Disinfects, cleans, and deodorizes in one labor-saving step.

Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, zoos, federally inspected meat and poultry plants, equine farms, tack shops, pet shops, airports, kennels, hotels, motels, poultry farms, turkey farms, dairy farms, hog farms, breeding establishments, grooming establishments, funeral homes, and households.

Disinfects, cleans, and deodorizes the following hard nonporous inanimate surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, plastic surfaces (such as polypropylene, polystyrene, etc.).

Use in:

- Federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, nonprocessing areas, and / or exterior areas. All surfaces must be thoroughly rinsed with potable water.
- Federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging material must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.
- Federally inspected meat and poultry plants as a disinfectant agent for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. Use product in accordance with its label. All surfaces must be thoroughly rinsed with potable water.

Recommended for use in tanning salons.

Recommended for use on (tanning beds), (and) (tanning equipment).

Effective against the following pathogens:

(Bacteria:)

Pseudomonas aeruginosa<sup>1</sup>  
Staphylococcus aureus<sup>1</sup>  
Salmonella choleraesuis

Acinetobacter calcoaceticus  
Bordetella bronchiseptica  
Chlamydia psittaci  
Enterobacter aerogenes  
Enterobacter cloacae  
Enterococcus faecalis – Vancomycin Resistant (VRE)  
Escherichia coli<sup>1</sup>  
Fusobacterium necrophorum  
Klebsiella pneumoniae<sup>1</sup>  
Legionella pneumophila  
Listeria monocytogenes  
Pasteurella multocida  
Proteus mirabilis  
Proteus vulgaris  
Salmonella enteritidis  
Salmonella typhi  
Salmonella typhimurium  
Serratia marcescens  
Shigella flexneri  
Shigella sonnei  
Staphylococcus aureus – Methicillin resistant (MRSA)  
Staphylococcus aureus – Vancomycin Intermediate Resistant (VISA)  
Staphylococcus epidermidis<sup>2</sup>  
Streptococcus faecalis<sup>1</sup>  
Streptococcus pyogenes  
<sup>1</sup> ATCC & antibiotic-resistant strain  
<sup>2</sup> antibiotic-resistant strain only

(Viruses:)

\*Adenovirus Type 4  
\*Hepatitis B Virus (HBV)  
\*Hepatitis C Virus (HCV)  
\*Herpes Simplex Type 1  
\*Herpes Simplex Type 2  
\*Human coronavirus  
\*HIV-1 (AIDS virus)  
\*Influenza A / Hong Kong  
\*Vaccinia  
\*Rubella (German Measles)  
\*Respiratory Syncytial Virus (RSV)

(Animal Viruses:)

\*Avian polyomavirus  
\*Canine distemper  
\*Canine parvovirus - at 1 oz. per gallon  
\*Feline leukemia  
\*Feline picornavirus  
\*Infectious bovine rhinotracheitis  
\*Infectious bronchitis (Avian IBV)  
\*Pseudorabies (PRV)  
\*Rabies  
\*Transmissible gastroenteritis virus (TGE)

(Fungi:)

Aspergillus niger  
Candida albicans  
Trichophyton mentagrophytes

(Note to reviewer: The following is considered optional marketing language.)

**(AREAS OF USE:)**

Use **Formulation HWS-512** in:

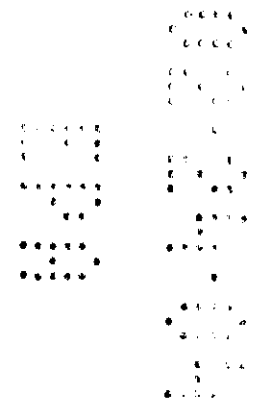
- Bathrooms
- Homes (households)
- Kitchens
  
- Dental offices
- Health Care Facilities
- Hospitals
- Medical Offices
- Nursing homes
  
- Day care centers
- Nurseries
  
- Bars
- Cafeterias
- Convenience stores
- Food processing plants
- Food storage areas
- Institutional kitchens
- Restaurants
- USDA inspected food processing facilities
  
- Athletic facilities
- Barber shops
- Business and office buildings
- Colleges
- Correctional facilities
- Dressing rooms
- Exercise facilities
- Factories
- Hotels
- Institutional facilities
- Institutions
- Locker rooms
- Motels
- Prisons
- Public facilities
- Public rest rooms
- Schools
- Shower and bath areas
- Salons (Beauty)
- Tanning Salons
  
- Camp grounds
- Play ground equipment

- Animal laboratories
- Dairy farms
- Farms
- Hog farms
- Kennels
- Poultry farms
- Pet animal quarters
- Pet shops
- Turkey farms
- Zoos
  
- Airplanes
- Airports
- Boats
- Buses
- Campers
- Cars
- Emergency vehicles
- Mobile homes
- Ships
- Taxis
- Trailers
- Trains
- Transportation terminals

**(TYPES OF SURFACES:)**

Use **Formulation HWS-512** on washable hard, nonporous surfaces of:

- Appliances, exteriors of
- Bathroom fixtures
- Bathtubs (Fiberglass)
- Cabinets
- Cages
- Chairs
- Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
- Conductive flooring
- Counters (countertops)
- Countertop laminates
- Desks
- Doorknobs
- Floors
- Foot Spas
- Garbage cans
- Highchairs
- Kennel runs
- Microwave ovens, exteriors of
- Outdoor furniture
- Refrigerators, exteriors of
- Refrigerated storage and display equipment



**PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.**

DILUTION: 1:512 (660 ppm quat)	¼ oz. per gallon of water
	½ oz. per 2 gallons of water
	1 oz. per 4 gallons of water
	1¼ oz. per 5 gallons of water
	2 oz. per 8 gallons of water

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

*(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)*

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

*(or)*

This product is not for use on medical device surfaces.

**DISINFECTION / CLEANING / DEODORIZING**

**DIRECTIONS:** Remove heavy soil deposits from surface. Then thoroughly wet surface with a use-solution of ¼ oz. of the concentrate per gallon of water. The use-solution can be applied with a cloth, mop, sponge, or coarse spray, or soaking. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished.

Food contact surfaces must be thoroughly rinsed with potable water. Do not use this product on utensils, glassware and dishes.

*(Note to reviewer: one of the following two statements will be used:)*

**BACTERICIDAL STABILITY OF USE-DILUTION:** Tests confirm that Formulation HWS-512, when diluted in 400 ppm hard water (via use of automatic dispensing devices), remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for (up to 7 days) (for up to one week) (for up to one month) (for up to 2 months) (for up to 3 months) (up to 4 months) (up to 5 months) (up to 6 months) (up to 7 months) (up to 8 months) (up to 9 months) (up to 10 months) (up to 11 months) (up to 12 months) (up to one year) when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

*(or)*

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

**TOILET BOWLS:** Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying use-solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first preclean to remove heavy soil, then remove or expel over the inner trap the residual bowl water. Pour in 3 oz. of the use-solution. Swab the bowl completely using a scrub brush or mop, making sure to get under rim. Let stand for 10 minutes or overnight, then flush.

**FUNGICIDAL DIRECTIONS:**

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

**MILDEWSTATIC INSTRUCTIONS:** Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply use-solution of ¼ oz. per gallon of water with a cloth, mop, sponge, or coarse spray. Make sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

**\*KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1)(associated with AIDS) or Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV OR HCV OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:**

**Personal Protection:** Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood / body fluids and during decontamination procedures.

**Cleaning Procedures:** Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of disinfectant.

**Contact Time:** HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (77°F) (room temperature). HBV and HCV are inactivated after a 10 minute contact time. Use a 10-minute contact time for all other viruses, fungi, and bacteria listed.

**Disposal of Infectious Materials:** Blood / body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

**SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION (BACTERICIDE) / VIRUCIDE / FUNGICIDE DIRECTIONS:**

Mix ¼ oz. of Formulation HWS-512 per gallon of water (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled.

**Note:** Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

**CLEANSING OF BODY SURFACES AND BODY ORIFICES OF HUMAN REMAINS:** This product removes body secretions, soil, and blood, along with their accompanying malodor, from the surfaces and orifices of human remains. Using a sponge or washcloth, bathe the entire body with a use-solution of ¼ oz. per gallon of water. A soft hand brush may be employed on surfaces other than the face. Prepare a fresh solution for each (cadaver) remains or when solution becomes visibly dirty or diluted.

**FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT**

DILUTION: 1:512                      ¼ oz. per gallon of water

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, cars, trucks, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.



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**VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:**

For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1/4 oz. of **FORMULATION HWS-512** per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. Ventilate buildings and other closed spaces. Thoroughly rinse all surfaces that come into contact with food, including equipment used for feeding or watering, with potable water before reuse. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

**FOR CANINE PARVOVIRUS ACTIVITY:**

Formulation HWS-512 is effective against Canine Parvovirus at 1/4 oz. per gallon. Follow Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions.

**CITRUS CANKER DISEASE CONTROL**

For prevention of Citrus Canker Disease through treatment of equipment: Effective against Xanthomonas axonopodis pv. citri (Citrus Canker Disease) at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, and field equipment including cargo area, wheels, tires, undercarriage hood, roof, fenders, and any other hard nonporous equipment taken into infested areas. Saturate surfaces with a 1:169 use-dilution (5 oz. per 6 1/2 gallons of dechlorinated water) (or equivalent dilution) (2000 ppm active quat) for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Clothing should be thoroughly rinsed or laundered before reuse. Footwear should be rinsed before reuse.

(Note to reviewer: If the container size is one gallon or less, the following Storage and Disposal directions will be used.)

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If the container size is greater than one gallon, the following Storage and Disposal directions will be used.)

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**Pesticide Storage**

Store in original container in areas inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

**Pesticide Disposal**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal**

(Plastic containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(Fiber Drums With Liner:) Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(Metal Container:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or dispose of by other procedures approved by state and local authorities.

